IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: **WAVE 1 CASES LISTED IN PLAINTIFFS' EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DEFENDANTS' EXPERT, REBECCA M. RYDER, M.D.

INTRODUCTION

In seeking to bar certain of Dr. Ryder's opinions on the safety of Prolift's design and materials issues such as pore size and degradation, Plaintiffs mischaracterize the scope of her opinions as well as the evidence on which they are based. Plaintiffs' Memorandum in Support of Motion to Exclude Certain Opinions and Testimony of Defendants' Expert Rebecca M. Ryder, M.D. [ECF No. 2021] ("Memorandum"). Dr. Ryder does not seek to opine on what may or may not be demonstrated under a microscope. Nor does she seek to opine on the technicalities of design protocols or how to measure a pore. Her opinions on these materials issues focus upon the *clinical impact* on patients of the use of these materials, which is squarely within her expertise as an experienced pelvic surgeon, and which has been well documented in the medical literature that Dr. Ryder has reviewed and analyzed.

When Dr. Ryder's opinions are considered within their proper scope, and in light of the broad sources of evidence that inform her opinions — most notably Level 1 peer reviewed

medical literature — her opinions survive Plaintiffs' challenge. Indeed, her opinions would be very informative to the jury and should be admitted at trial.

DR. RYDER'S PROFESSIONAL BACKGROUND AND EDUCATION

Dr. Ryder is a board certified obstetrician/gynecologist with over 18 years of experience treating women suffering from pelvic floor disorders such as pelvic organ prolapse and incontinence. Rebecca M. Ryder, M.D., Dep. (Mar. 21, 2016) ("Ryder Dep.") at 150:11-151:3, Exhibit D to Plaintiffs' Motion [ECF. No. 2016-4]. She has performed over 1,000 surgeries for the repair of pelvic organ prolapse and/or incontinence, of which approximately 100 are Prolift procedures. Expert Report of Rebecca M. Ryder, M.D., Feb. 27, 2016 ("Ryder Report") at 2, Exhibit B to Plaintiff's Motion [ECF. No. 2016-2].

In addition to mesh surgeries to treat prolapse, Dr. Ryder has also performed many other types of prolapse repair surgeries including: vaginal, abdominal and laparascopic hysterectomy, uterosacral ligament suspension, native tissue repairs, paravaginal defect repairs both abdominally and vaginally, biologic graft reinforced repairs, abdominal sacral colpopexy and vaginal mesh procedures. *Id.* She has also performed numerous types of anti-incontinence surgeries including retropubic urethropexy, autologous fascia lata and biologic graft slings, tension-free vaginal tape (TVT), and transobturator and single incision mesh slings. Dr. Ryder continues to use transvaginal mesh repair kits with polypropylene implants through today, both to treat prolapse and stress urinary incontinence. In fact, about 15-20% of the approximately 1,000 pelvic surgeries she has performed have employed a polypropylene mesh implant. Ryder Dep. at 134:8-13 [ECF. No. 2016-4].

Dr. Ryder received her medical degree from the University of North Carolina at Chapel Hill in 1993 where she also did her residency in Obstetrics and Gynecology. Ryder Report at 1

[ECF. No. 2016-2]; CV of Rebecca Ryder, M.D. ("CV") at 1, Ex. C to Plaintiffs' Motion [ECF. No. 2016-3]. After completing her residency with distinction, Dr. Ryder joined the faculty at Duke University Medical Center with a joint appointment in OB/GYN and Family Medicine. Ryder Report at 1-2 [ECF. No. 2016-2]. She began her subspecialty in Urogynecology while at Duke. *Id.* at 1. In 1994, she began teaching at Eastern Virginia Medical School and continued training in urogynecology. *Id.* at 1-2. Dr. Ryder began private practice in Chesapeake, Virginia in 1998 where she treats woman for gynecologic and urogynecologic conditions including "uterine prolapse, cystocele ('dropped bladder'), vaginal prolapse, rectocele, enterocele (vaginal hernia) and vaginal prolapse after hysterectomy, as well as stress and urge incontinence and fecal incontinence." *Id.* at 2. Dr. Ryder is board certified in both obstretrics/gynecology and in Female Pelvic Medicine and Reconstructive Surgery. CV at 2 [ECF. No. 2016-3]. Dr. Ryder has treated pelvic organ prolapse with transvaginal mesh repair throughout her years of practice and continues to do so today. Ryder Dep. at 150:20-151:3 [ECF. No. 2016-4].

DR. RYDER'S TRAINING ON AND DECISION TO USE PROLIFT

Dr. Ryder was formally trained on Prolift in April of 2005. Ryder Dep. at 87:15-17 [ECF. No. 2016-4]. However, by the time she was trained in Prolift, Dr. Ryder was already familiar with Gynemesh PS and had already been using Gynemesh PS in the treatment of patients with pelvic organ prolapse. *Id.* at 154:24-155:6. During her Prolift training, in addition to being taken through the steps of the procedure, Dr. Ryder learned the history of the TVM procedure and its evolution into the Prolift, reviewed early clinical data from the TVM study in France, and heard her preceptor's own personal experiences and patient outcomes when using the Prolift. *Id.* at 91:15-92:7. Although Dr. Ryder was confident that she had been adequately

trained on the use of Prolift, she conducted her own research before reaching her final decision to use Prolift on her patients. *Id.* at 92:8-14; 99:24-100:10.

In her Report, Dr. Ryder states that after her training she "decided to investigate further and ultimately used the Prolift system in my patients due to the positive experience of leaders in the field, the consistency of the product and the reproducibility of a standardized POP repair procedure." Ryder Report at 13 [ECF. No. 2016-2]. During her deposition, Dr. Ryder testified that these experienced leaders included the French TVM study surgeons:

> Q: In your decision to use Prolift, was the experience of the French TVM surgeons relevant to your assessment of the product?
>
> A: Yes.
>
> Q: And how was it relevant?
>
> A: Well, I wanted to know the experience of the people who were instrumental in designing the product, what their experience with patients had been, what their experiences with interoperative and postoperative complications were.
>
> Q: And was the fact that the TVM data involved the same mesh as Prolift relevant to your assessment?
>
> A: Yes.

Ryder Dep. at 155:21-156:9 [ECF. No. 2016-4].

Both in her Report and deposition, Dr. Ryder testified to doing additional research on Prolift before using it on her patients:

> Q: So I want to know what all you did between your introduction and training on the product from April 11, 2005, to, I think it's June 7, 2005, to investigate the product.
>
> A: I did some medical research. I did, I believe PubMed searches, looked at things that had been presented, and I don't remember if there's another meeting in there. I don't remember when AUGS

> was that year. Could have been something like that. Talked to other people, but probably talked to Jon Crockford about it.

Id. at 99:24-100:10; Ryder Report at 13 ("I decided to investigate further and ultimately used the Prolift system in my patients due to the positive experience of leaders in the field, the consistency of the product and the reproducibility of a standardized POP repair procedure.") [ECF. No. 2016-2].

While Plaintiffs claim that they "do not challenge her qualifications" as a board certified ob/gyn and specialist in female pelvic medicine, Memorandum at 1 [ECF. No. 2021], they nonetheless seek to paint an inaccurate picture in their moving brief that Dr. Ryder was 'trained for one day' on Prolift in an Ethicon-sponsored event. *Id*. at 4. As the discussion above clearly demonstrates, this 'one-day' event is but one small component of a 20-year history of surgical training, including her residency and 18 years in private practice performing surgeries to treat prolapse and stress urinary incontinence, many of which have employed transvaginal mesh.

BASES OF DR. RYDER'S OPINIONS

The first paragraph of Dr. Ryder's general report on Prolift sets forth the sources of information and evidence that form the basis of her opinions in this litigation: "My opinions set forth in this report are made to a reasonable degree of medical certainty, and are based on information and knowledge I have acquired from my education, training, personal experience in private practice, teaching, discussion and interaction with other pelvic surgeons in professional activities and conferences, research and review of medical literature and records." Ryder Report at 1 [ECF. No. 2016-2]. In addition to in-person training on Prolift held in April of 2005, Dr. Ryder also conducted her own research into the effectiveness and design of the Prolift before she was retained as an expert in this case. Ryder Dep. at 99:24-100:10 [ECF. No. 2016-4]; Ryder Report at 13 [ECF. No. 2016-2].

In addition to the research that Dr. Ryder performed in deciding to use Prolift, Dr. Ryder has also reviewed well over 300 medical articles in preparing her expert report. Materials Reviewed List ("Materials Reviewed"), Ex. E to Plaintiffs' Motion [ECF. No. 2016-5]. This list included some articles provided to Dr. Ryder with which she was already familiar, and some that she added to the list herself. Ryder Dep. at 43:6-46:4; 151:12-21 [ECF. No. 2016-4].

Despite her extensive surgical experience implanting Prolift, it is clear from her general report and materials list that her opinions in this litigation are based largely on her extensive review of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials, not to mention public statements by medical societies in the fields of urology. Half of Dr. Ryder's Report (Ryder Report at 9-13; 17-21, Attached List of RCTs, [ECF. No. 2016-2]) is dedicated to an analysis of the clinical literature that has evolved over twenty years on polypropylene mesh. This includes a detailed review of the peer reviewed medical literature assessing Prolift in particular, as well as other surgical treatment options for prolapse and potential complications. By contrast, a much smaller portion of her Report is dedicated to her personal surgical experience or to the complication she has observed solely in her patients.

Her opinions are also based on a host of additional informational sources, which she summarized in her deposition:

> Q: Is it fair to say that your opinions in this case today, from what I'm hearing, it is based upon your clinical experience and your review of the literature?
>
> A: It is based on my review of the literature, my attendance at professional societies, my discussion with colleagues, my reading of the FDA reports. It is a global impression based on many, many factors.

Ryder Dep. at 105:17-106:2 [ECF. No. 2016-4]. These sources included the various FDA public notifications and statements on the use of mesh to treat prolapse and stress urinary incontinence,

numerous medical society statements on the use of mesh to treat pelvic floor disorders. Material Reviewed at 37-40 [ECF. No. 2016-5].

LEGAL STANDARD

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. DR. RYDER IS QUALIFIED TO OPINE AS TO THE DESIGN OF PROLIFT BASED ON HER EXTENSIVE REVIEW OF THE RELEVANT MEDICAL LITERATURE, AS WELL AS HER SURGICAL EXPERIENCE AND TRAINING.

Plaintiffs claim that Dr. Ryder is not qualified to offer an opinion on whether Prolift was defectively designed because she is not trained in a device manufacturer's internal workings in bringing a new device to market. Memorandum at 10-12. However, her opinions on the safety of Prolift and the benefits of its design derive not from 'design protocols' and 'design requirement matrices', but from the actual performance of the device in real patients – in Dr. Ryder's own surgical experience and that of hundreds of other doctors as publicly reported in Level 1 peer reviewed medical literature following thousands of patients.

As discussed above, Dr. Ryder has extensive experience in treating pelvic floor disorders over the past 18 years. Ryder Dep. at 150:11-13 [ECF. No. 2016-4]. Dr. Ryder has performed over 1,000 surgeries for the repair of pelvic organ prolapse and/or incontinence, including procedures using Gynemesh PS and approximately 100 Prolift implants. Ryder Report at 2 [ECF. No. 2016-2]. She continues to use transvaginal polypropylene mesh kits to treat prolapse to this day. Ryder Dep. at 150:17-151:3 [ECF. No. 2016-4]. This Court has already decided that a physician's "extensive experience with pelvic floor disorders and the use of mesh to treat such

disorders qualifies him to render opinions on such issues, notwithstanding his lack of expertise in the particular areas of product design or biomaterials." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). Thus, based on the Court's ruling in *Bard*, Dr. Ryder's lack of familiarity with "design control, design requirement matrix, or F[M]EA" (Memorandum at 11) does not disqualify her from opining on whether Prolift's design is safe and effective as used in pelvic organ prolapse patients, in light of her surgical experience.

Further, Plaintiffs' assertions that Dr. Ryder had no methodology behind her opinions are simply untrue. Her methodology is a careful review of the highest levels of medical literature evaluating Prolift and more generally the transvaginal use of polypropylene mesh to treat prolapse. The hundreds of published studies she has reviewed include sources at the highest levels of scientific evidence, including the 2016 Cochrane Review meta-analyses which assessed 37 RCTs in which 4,023 patients received treatment pelvic floor repair, of which nearly 2,500 patients underwent transvaginal mesh repair. Ryder Report at 19, *citing* Maher et al. (2016) Summary Cochrane Review: Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse [ECF. No. 2016-2]. Dr. Ryder's review also included other meta-analyses including the 2013 edition of the Cochrane Review and the 2011 meta-analysis published by the Society of Gynecologic Surgeons' Systematic Review Group on the "Incidence of and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials." Ryder Report at 18-20, *citing* 2013 Cochrane Review and Abed 2011 [ECF. No. 2016-2].

In addition to these meta-analyses, Dr. Ryder also reviewed and analyzed eight randomized controlled trials, including Altman 2011, Sokol 2012, and da Silveira 2014, covering 1,215 patients and evaluating Prolift against native tissue repairs such as colporrhaphy and

sacrospinous ligament fixation. Dr. Ryder attached the list of the trials she reviewed to the end of her Report. *Id.,* Attachment to Report. Dr. Ryder's Report recognizes what is well known in her field, that "Prospective randomized controlled trials (RCTs) are considered the highest level of evidence in clinical studies. . . ." Ryder Report at 17 [ECF. No. 2016-2]. Based on her review of these RCTs, she concluded that: "These best-quality research studies are nearly universally consistent in their findings of better post-operative results, less recurrent prolapse, and no increased dyspareunia with the use of the Prolift system. These RCTs suggest Prolift to be the more durable operation with better results for the majority of patients." *Id.* at 18.

Plaintiffs are also incorrect in suggesting that Dr. Ryder did not review internal company analyses in arriving at her opinions. As her materials list reflects, she reviewed and considered various such documents, including: Ethicon's Clinical Expert Report for Prolift; Ethicon's internal Clinical Study Reports from the prospective transvaginal mesh studies; Ethicon's Biocompatibility Risk Assessment for Prolift dated January 19, 2005; and Ethicon Final Report, PSE Accession No. 00-0035, An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035) dated July 11, 2001. Materials Reviewed at 33-35 [ECF. No. 2016-8].

It is therefore difficult to understand how Plaintiffs can attack Dr. Ryder for lacking methodology when in fact she relies not only on her surgical experience and company documents, but most importantly, on actual patient outcomes reported in the highest levels of peer reviewed clinical studies to support her conclusion that Prolift is safe and not defectively designed. For these reasons, Dr. Ryder's opinion on design defect should not be excluded.

II. DR. RYDER IS QUALIFIED TO OPINE AS TO THE SAFETY OF POLYPROPYLENE AND PORE SIZE OF THE MESH USED IN PROLIFT.

Plaintiffs contend that Dr. Ryder cannot opine on the use of polypropylene material, mesh pore size, and risk of infection because Dr. Ryder is not qualified to render such opinions and the opinions are not reliable. Memorandum at 12-14. In particular, Plaintiffs contend that because Dr. Ryder did not know who within Ethicon evaluated the safety of Prolift, whether Ethicon complied internally with its safety and efficacy standards, and has never herself tested or studied polypropylene mesh as a clinical investigator, she is not qualified to make an opinion on the mesh. *Id.* However, an expert is not required personally to perform studies and experiments to opine on a matter. As this Court has found, when an expert relies on scientific literature, as well as her own knowledge and experience, her opinion is considered reliable. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 626 (S.D. W. Va. 2013) (finding an expert's opinion reliable where the expert's report suggested "that he relied not only on his knowledge and experience, but also on scientific literature.") While these matters may be proper for cross-examination, they do not form a basis to exclude her testimony.

Plaintiffs' argument fails to recognize that the best source of evidence to assess the safety of the material properties of polypropylene is the extensive body of medical literature that evaluates its use in real patients over time – precisely the body of information that Dr. Ryder researched in formulating her opinions. Dr. Ryder's role is not to opine on the engineering aspects of pore size; she is a surgeon who has observed the clinical implications of polypropylene mesh in medical literature and in her own practice, as described in detail above.

Although Plaintiffs characterize her opinions as "arbitrary," her opinions are based on a host of factors, including a review of the relevant medical literature:

> Q: Opinion No. 2 is that "Gynecare, Gynemesh PS used in Prolift is an appropriate, effective and safe material for use in this indication. Polypropylene mesh and sutures have been used as an implant for decades. The pore size is sufficiently large to allow for proper tissue ingrowth and has not presented increased risk of infection, particularly in relationship to other implants. Can you explain to me what the basis for that opinion?
>
> A: The review of the medical literature, the presentations at international meetings, national meetings, the physician statements, and by clinical experience.

Ryder Dep. at 156:16-157:5 [ECF. No. 2016-4].

Thus, Dr. Ryder is not only qualified to opine on the safety of the polypropylene mesh used in the Prolift, including the use of polypropylene material, mesh pore size, and risk of infection, but her opinions are reliable as they are based on a review of peer-reviewed medical literature along with her clinical experience as a surgeon.

III. DR. RYDER IS QUALIFIED TO RENDER OPINIONS ABOUT THE CLINICAL EFFECTS (OR ABSENCE THEREOF) OF ALLEGED DEGRADATION.

Plaintiffs further contend that Dr. Ryder is unqualified to opine on whether the mesh in Prolift degrades *in vivo*. Memorandum at 14-18. Specifically, Plaintiffs claim that she "does not have any specialized training specifically related to polypropylene or the scientific, chemical or structural make-up of the Prolift device. *Id.* at 15. However, Dr. Ryder does not need to demonstrate such knowledge to opine on the clinical significance of any alleged degradation. As this Court has previously ruled specifically regarding opinions on degradation, "because [a doctor] cannot describe the chemical properties of polypropylene does not render him unqualified to testify that he has not experienced degradation in his practice." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 706-707 (S.D. W. Va. 2014).

To be clear: Dr. Ryder does not seek to opine regarding any process that occurs on a microscopic level *in vivo*. Rather, her opinions on materials and pathology issues are limited to the *clinical impact* of those alleged processes based on the detailed review of medical literature that she has conducted, as well as her surgical experience in her patients. In her Report, Dr. Ryder opines that "[t]he body of clinical data for Prolift (and TVT, for that matter) does not support the conclusion that PROLENE® Soft mesh degrades in the body *in any manner that has a clinical impact on the patients*." Ryder Report at 21 (emphasis added) [ECF. No. 2016-2]. Such opinions are entirely appropriate.

Plaintiffs are also wrong that Dr. Ryder's expert report provides no scientific basis or methodology supporting her opinion and is based "solely on her speculative assumption." Memorandum at 15. To the contrary, Dr. Ryder has reviewed hundreds of published studies, in part to find substantiation in the clinical literature for Plaintiffs' claims regarding degradation. Materials List [ECF. No. 2016-5]. With respect to these issues, her opinions derive from what she has concluded is the absence of evidence in the medical literature to support Plaintiffs' theories. Specifically, she opines that: "[t]he body of clinical data for Prolift (and TVT, for that matter) does not support the conclusion that PROLENE® Soft mesh degrades in the body in any manner that has a clinical impact on patients." Ryder Report at 21 [ECF. No. 2016-2].

When faced with a similar expert opinion in *Huskey*, this Court found that "district courts have 'considerable leeway' in applying *Daubert*'s reliability factors" and that "this type of opinion is obviously not subject to testing or peer-review." 29 F. Supp. 3d at 726 (S.D. W. Va. 2014) (citing *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 152 (1999)). Because an opinion on the clinical significance of degradation is not subject to testing or peer-review, "clinical experience and review of relevant literature is a sufficiently reliable method of forming this

particular opinion." *Huskey*, 29 F. Supp. 3d at 735 (citing *DeKeyser v. Thyssenkrupp Waupaca, Inc.*, 747 F. Supp. 2d 1043, 1050 (E.D. Wis. 2010)); *see also Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, *5 (S.D. W. Va. Apr. 28, 2016) (finding that a urologist's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction.")

While this Court has observed that "Absence of evidence is not evidence of absence," *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 583 (S.D. W. Va. 2014), the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where a physician examines the evidence outside of his own experience, analyzing studies and literature and Level 1 evidence, the stronger the conclusion becomes that there is no risk. Thus, while absence of evidence in a limited sampling pool of a single physician's experience may not be proof of absence, absence of evidence in a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, is sound evidence of absence. *See also Huskey*, 29 F. Supp. 3d at 735; *Trevino*, 2016 WL 1718836, at *5.

As described in detail above, the literature review Dr. Ryder performed entailed the highest levels of studies observing thousands of patients. In addition, Dr. Ryder's opinion on degradation is based on the histologic study performed by the Woodruff et al. 2008, "Histologic Comparison of Pubovaginal Sling Graft Materials: A Comparative Study," in which the authors concluded that the polypropylene grafts had "no demonstrable graft degradation." Ryder Report at 21 [ECF. No. 2016-2].

Beyond her literature review, Dr. Ryder also discusses in her Report the "Frequently Asked Questions by Providers" jointly issued by the American Urogynecological Society (AUGS) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstructions's (SUFU), two prominent medical societies in this field. Ryder Report at 10-11 [ECF. No. 2016-2]. In that publicly-issued statement, AUGS/SUFU specifically conclude that the allegation of degradation is not supported by the extensive peer reviewed literature on polypropylene, which has followed patients out to seventeen years. *Id.* at 10; Ex. A to Defs.' Memorandum, AUGS/SUFU March 2014 FAQ to Providers at 1-2. In support of its statement, AUGS and SUFU cite the 17-year follow up study by Nilsson et al. on Gynecare TVT, which is made of the same PROLENE® polypropylene as Prolift, but in a different knit. Given that both Prolift and TVT are made of PROLENE®, it is entirely appropriate that Dr. Ryder would rely upon the clinical history of TVT in opining that degradation, if it exists, has no clinical impact upon patients. In her report, Dr. Ryder explains how the Prolift evolved from the use of polypropylene mesh in TVT. Ryder Report at 12 [ECF. No. 2016-2]. In fact, her opinion is reinforced by the Board of Directors of AUGS and SUFU in their Joint Statement. *Id*. at 10, 12.

For this reason, Plaintiffs' argument that Dr. Ryder should not be permitted to reference the clinical history of TVT should be rejected. Memorandum at 18. Simply put, Plaintiffs should not be permitted to lodge the claim that PROLENE® degrades in the human body and then seek to bar Ethicon's experts from discussing the decades-long history of the use of PROLENE® mesh as slings and for abdominal prolapse repair procedures, not to mention the even longer history of use of PROLENE® sutures. Ryder Report at 10-13 [ECF. No. 2016-2].

It should be noted that in attacking Dr. Ryder's methodology, Plaintiffs state that Dr. Ryder "did not ask Ethicon to provide her with all of the information that they have concerning

degradation" and that Dr. Ryder asserted that "there is nothing she could learn about the material used in Ethicon's TVT or TVT-O products, or that she could see in the medical literature about polypropylene degradation, that would change her opinion." Memorandum at 16. Although Plaintiffs provide citations to Dr. Ryder's deposition testimony to support these assertions, this testimony cannot be found either at their citations or anywhere in the deposition transcript.

For these reasons, Dr. Ryder is qualified to offer opinions about the medical and clinical significance of any alleged degradation.

CONCLUSION

For the reasons set forth above, Plaintiffs' motion to exclude certain opinions and testimony of Defendants' Expert Rebecca M. Ryder should be denied.

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/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

/s/ Maha Kabbash
Maha Kabbash
Riker Danzig Scherer Hyland &
Perretti, LLP
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
(973) 451-8472
mkabbash@riker.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Maha Kabbash
Maha Kabbash